APR 2 4 2013

510(K) SUMMARY

K130896

Applicant (Manufacturer)
Synovis Surgical Innovations, a division of Synovis Life Technologies, Inc.
2575 University Ave. W.
St. Paul, MN 55114-1024 U.S.A.
Ph: (651) 796-7300 (Main)
Fax: (651) 642-9018 (Main)

Contact (Manufacturer)
Stephani K. Ayala
Regulatory Affairs Specialist
Synovis Surgical Innovations, a division of Synovis Life Technologies, Inc.
2575 University Ave. W.
St. Paul, MN 55114-1024 U.S.A.
Ph: (651) 796-7339 (Direct)
Fax: (651) 642-9018 (Main)
E-mail: stephani_ayala@baxter.com

Date Submission Prepared
03/26/2013

Device Trade Name
- Vascular Probe
- Vascular Probe ES

Common Name
Vessel Dilator, Surgical

Classification Name
- Vessel Dilator, Surgical
- 21 CFR §870.4475
- Product Code: DWP

Predicate Device
Synovis Life Technologies Inc. (previously doing business as Bio-Vascular, Inc.), Robicsek Probe/Retractor; 510(k) K910682

Device Description
The Vascular Probe is a sterile, single use, disposable device with a polyurethane coated streamline bulb on each end of a flexible polycarbonate or polycarbonate-polyurethane shaft. The bulbs are of different size on each end of the Vascular Probe. An appropriately-sized bulb is inserted either proximally or distally through the arteriotomy to probe the interior of the vessel and may be used by the surgeon to retract the vascular wall.

The Vascular Probe is packaged in a double sterile barrier. The contents of the unopened, undamaged container are sterile.

Statement of Intended Use

The Synovis Vascular Probe is intended for use during coronary and peripheral vascular surgery to probe blood vessels distally and proximally for blockages, to measure the internal diameter of vessels, and to act as an intravascular retractor.

Summary/Comparison of Technological Characteristics

The Vascular Probe is acting as its own predicate device, and is therefore substantially equivalent, having the same technological characteristics and indications for use.

A new vinyl resin utilized in the colorant of the polyurethane coating was identified for manufacturing the Vascular Probes and is the subject of this submission. The Vascular Probe is a blood contacting device. The length of time the Probe is in contact with the body is typically less than 15 minutes (i.e. transient use). Testing conducted to assure the Probe Tips, manufactured with the new vinyl resin, remain safe for its intended use included Biocompatibility and Tensile strength testing.

Biocompatibility testing was performed in accordance with ISO 10993-1 (*Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process).* The testing performed on the Vascular Probes demonstrated the devices continue to be biocompatible and safe for their intended use.

Tensile strength testing was conducted on the Vascular Probes manufactured with the new vinyl resin and concluded that the Probes continue to meet the current Vascular Probe finished device specifications.

Conclusion

The safety and performance of the Vascular Probes was evaluated through biocompatibility and bench testing. The bench testing results support the performance requirements for the Vascular Probes manufactured with the new vinyl resin. Biocompatibility testing was performed in accordance with ISO 10993-1 and demonstrated the Vascular Probes remain biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 24, 2013

Synovis Life Technologies, Inc.
c/o Stephani Ayala
2575 University Ave. W.
St. Paul, MN 55114 US

Re: K130896
Trade/Device Name: Vascular probe
Regulation Number: 21 CFR 870.4475
Regulation Name: Vessel Dilator, Surgical
Regulatory Class: Class II
Product Code: DWP
Received: April 1, 2013

Dear Stephani Ayala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K130896

Device Name: Vascular Probe

Indications for Use:

The disposable Vascular Probe is intended to be used during coronary and peripheral vascular surgery to probe blood vessels distally and proximally for blockages, to measure the internal diameter of vessels, and to act as an intravascular retractor.

Prescription Use _X____ OR Over-The-Counter Use_____
Per 21 CFR 801.109

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G Hillebrenner